

# Exhibit 8

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# **Corporate Compliance Quarterly Report to Board of Directors**

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**February 8, 2008**  
**Vice President, Corporate Compliance**  
**Bert Weinstein**



# Agenda

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- Purdue's CIA and AG Agreement
- Hotline and Other Inquiries
- Institutional Policies
- State Law Requirements
- National Sales Meeting
- 2008 Workplan



# CIA and AG Agreement Status



- CIA Day 120 Implementation Report complete and timely submitted to OIG on 11/28/07
- OIG considering exclusion of Chief Legal Officer
  - Responded with plan on 12/4/07
  - No further communications to Purdue from OIG
- IRO “relationship” very good, and Workplan preparations well along
- Annual Report Submission to OIG – Due 9/29/08
- Purdue in compliance with AG Agreements
  - Abuse & Diversion Detection (ADD) training - current
  - HCP letter process - current



# IRO Workplan - 1<sup>st</sup> Reporting Period



- The First Reporting Period is 7/31/07-7/30/08
- Two Transactions Reviews will cover the last six months of this period
  - Any Field Contact Reports suggesting improper promotion
  - Rep-generated inquiries related to OxyContin in Medical Services' Database
- IRO Huron will prepare a draft report for Purdue's review and comment; then finalized; we submit report to OIG
- Upcoming -Systems Reviews begin in the Second Reporting Period; Transactions Reviews continue
  - Nine Systems / SOPs - e.g., contracts with HCPs, Grants, Material Review, Discontinuation of Material, Employee Discipline

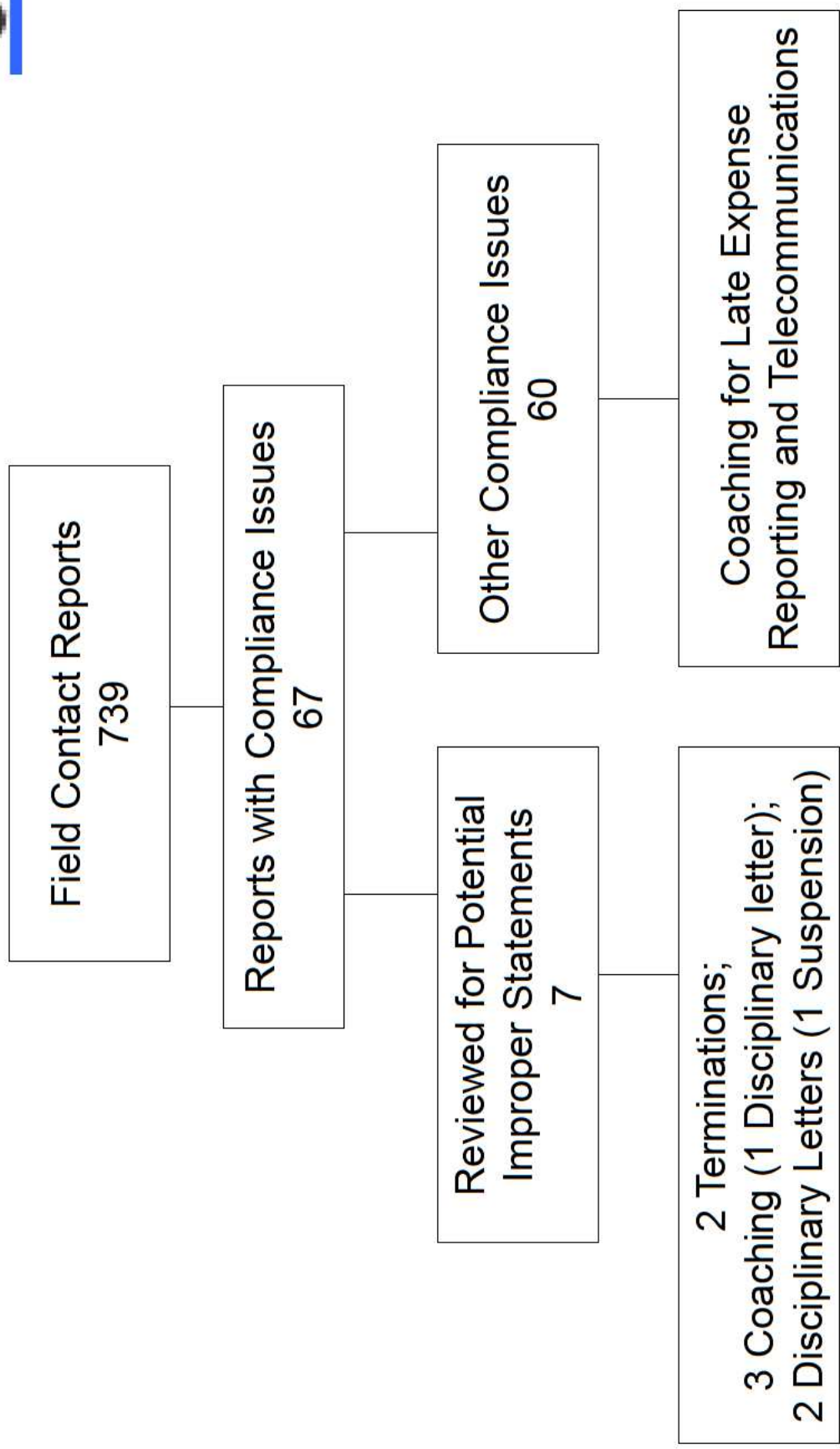
# Compliance Audit Plan



## Compliance Audits for 2008 focus primarily on preparation for IRO Reviews:

- Medical Services (incl. SOPs for approval and handling of requests for off-label information, and Sales Force-related Inquiries)
- Use of Materials by Field Sales (incl. processes for warehousing and discontinuing Materials)
- Material Review Process
- Discipline Database (consistent and appropriate discipline)
- Review of RCP Compensation Program
- Grants and Charitable Contributions
- Promotion Monitoring Program (Field Contact Reports)
- Sales Rep Handling of requests for information about off-label uses of products
- Medical Liaisons

# CIA “FCR” Monitoring Q3-4/07





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# Hotline Calls and Other Inquiries

## 4Q07

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# Hotline and Other Inquiries 4Q07



- Investigated 86 inquiries in 4Q07; four had compliance implications:
  - 3 Sales & Marketing Matters – sales slide deck review process; potential “gift” to son of HCP; and rep’s personal visit with spouse to HCP in another territory raised compliance concerns
  - 1 Other Matter - Medical Services received call from a pharmacy that a rep made improper claim about OxyContin
- These four matters were all “direct” inquiries – not anonymous hotline calls
- A Call Log is maintained of all Corporate Compliance inquiries, and is available for review

# Examples of non-CIA Monitoring



- **Sales Representative overdue expense reporting – *Warning***

Through routine monitoring efforts, discovered rep failed to timely enter and attribute HCP expenses, violations of Purdue policies with potential for non-compliance with state reporting laws. Written warning letter issued to rep.

- **Sales Representative submitting false reports - *Termination***

Corporate Compliance involved in termination of rep resulting from rep falsely reporting physician calls, three of which included false adverse event reports.

- **Potential inappropriate interaction with HCP - *Coaching***

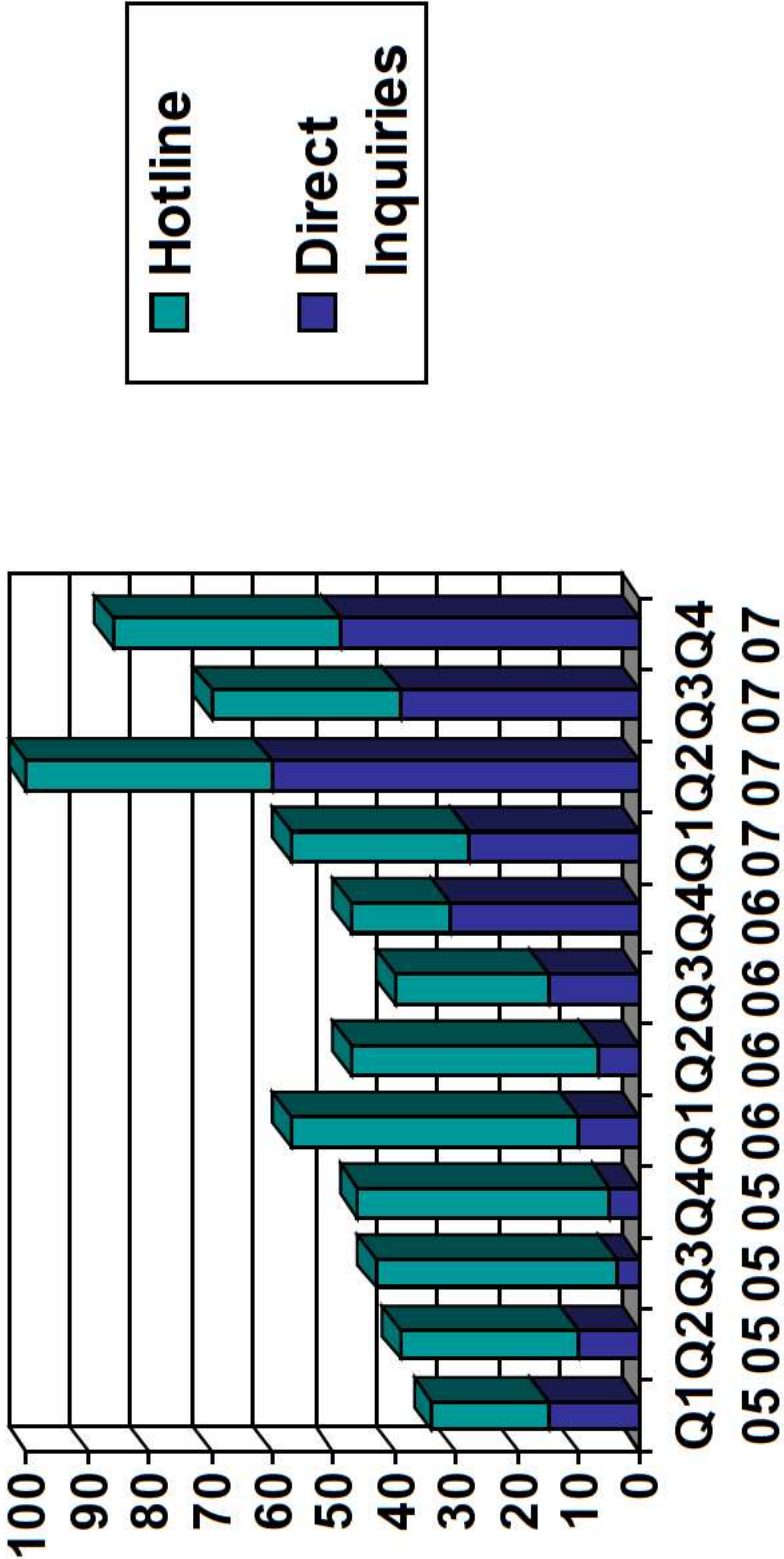
A rep reported making arrangements for a well-known musician to provide a private guitar lesson to the terminally ill son of a prescriber rep called on, raising potential Anti-Kickback concerns. Corporate Compliance investigated the matter and determined “intent” element of the Anti-Kickback Statute not met. Corporate Compliance provided coaching.



## New Investigations Underway

- Uniphyl batch process at Totowa – GMP-related questions raised by employee
- Reps received outdated Package Inserts from warehouse, and brought to attention of Sales management
- OxyContin Package Insert typo – error spotted after distribution to reps

# Inquiries by Quarter (1Q05 – 4Q07)





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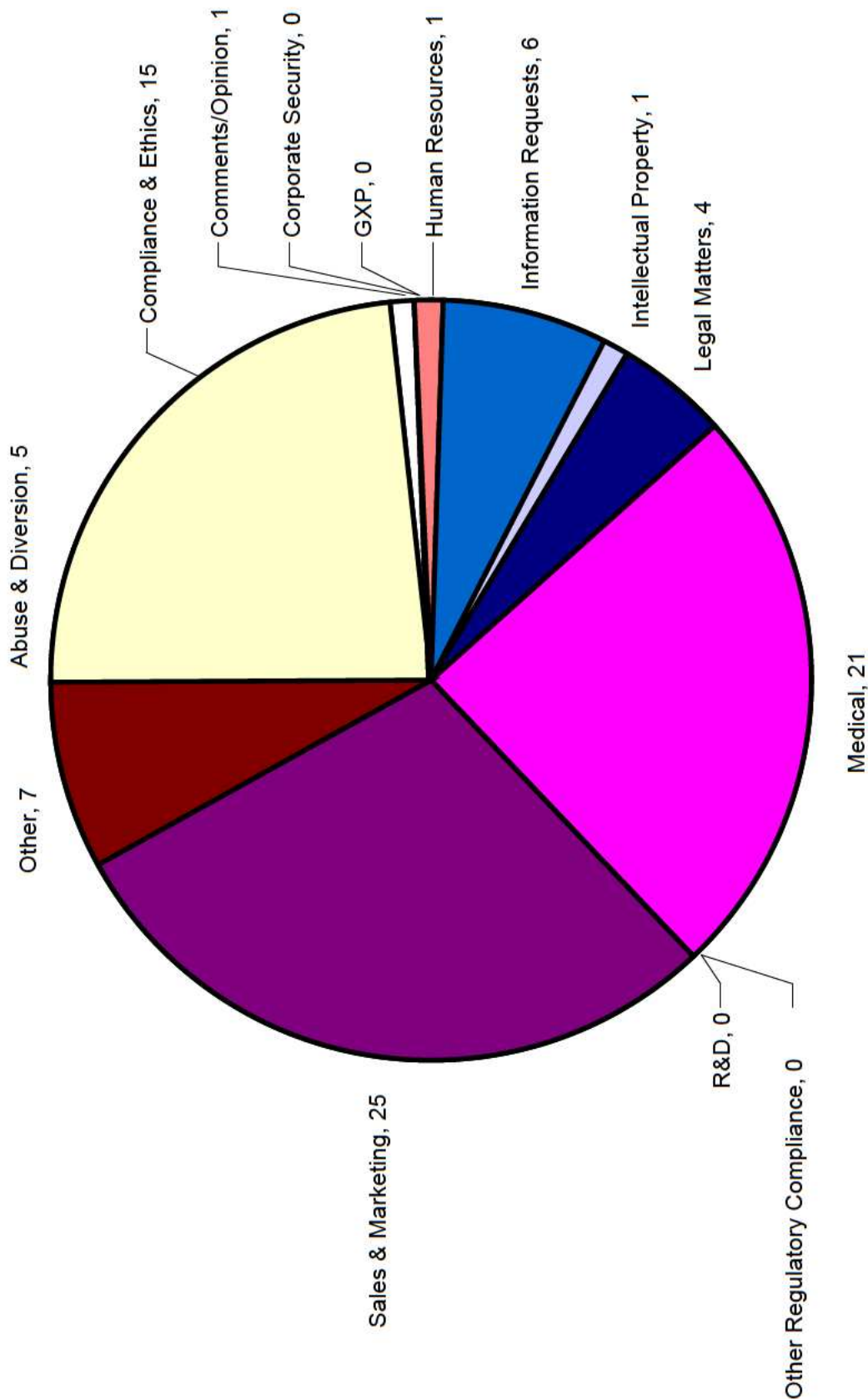
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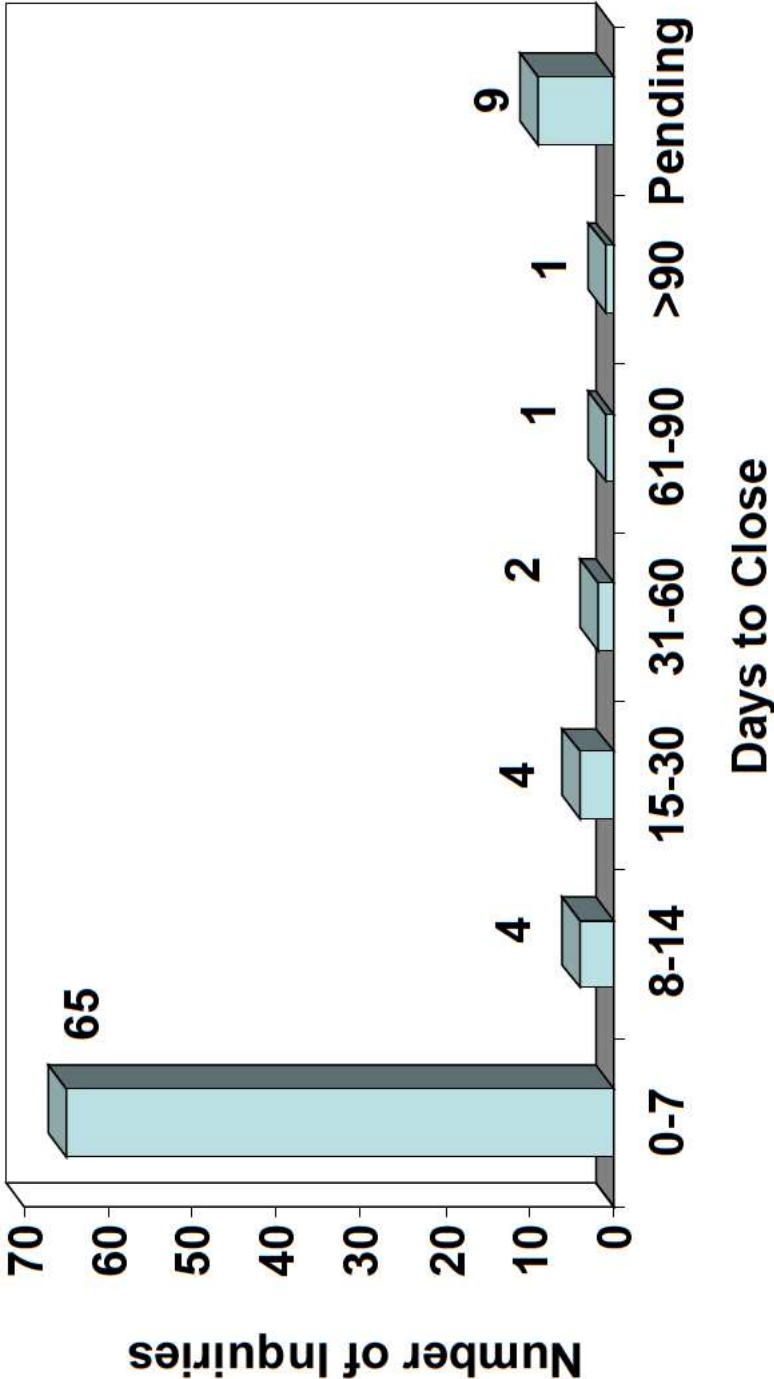
# 4Q07 Compliance Inquiries



# Inquiry Response Time



Days to Close Inquiries 4Q07 (as of 1/25/08)



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# Expanding Universe of Institutional Policies

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# Institutional Policies – a troubling trend



- What are “Institutional Policies?”
- Two Recent examples:
  - Health Partners:
    - No office hour calls on MDs – meet on free time
    - No calling on pharmacy – advance permission required
  - St Mary’s Duluth Clinic:
    - No food, no studies, no leave-behinds
    - Not allowed in the building without an appointment
    - Mail in required to propose an appointment
- Other new rules include training and testing requirements, proof of vaccinations, payments of fees
- These requirements have been multiplying
  - internal “pharm free” movement
  - new third party business model



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# State Law Requirements

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# State Law Reporting

- 2007 Filings
  - All filings required in 2007 timely made and complete
  - No compliance issues
- Pending Legislation – federal and states
  - Prescriber Privacy Laws
  - Price Reporting
  - Clinical Trials Reporting
  - Gift/Meals Reporting
  - Marketing Cost Reporting



# New State Reporting Requirements



- **DC - Safe Rx Amendment Act of 2008**
  - DC is first to require licensure of reps
  - Covered by a new Code of Ethics
  - Bachelor's in pharmacy / chemical / physical / biological science – grandfathering of reps in DC more than 12 months
  - Awaiting Congressional review; approval expected
- **Nevada – Compliance Program Law**
  - Report requires adoption of code of conduct (PhRMA), training program and investigation policy, audit of program
  - Report due 6/1/08
- **West Virginia – Marketing Disclosure Rule**
  - Anticipated legislative approval early April
  - In the interim, required to report marketing expenses pursuant to “Emergency Rule”
  - Report due 3/1/08

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# National Sales Meeting

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# Compliance Talks to Four Regions

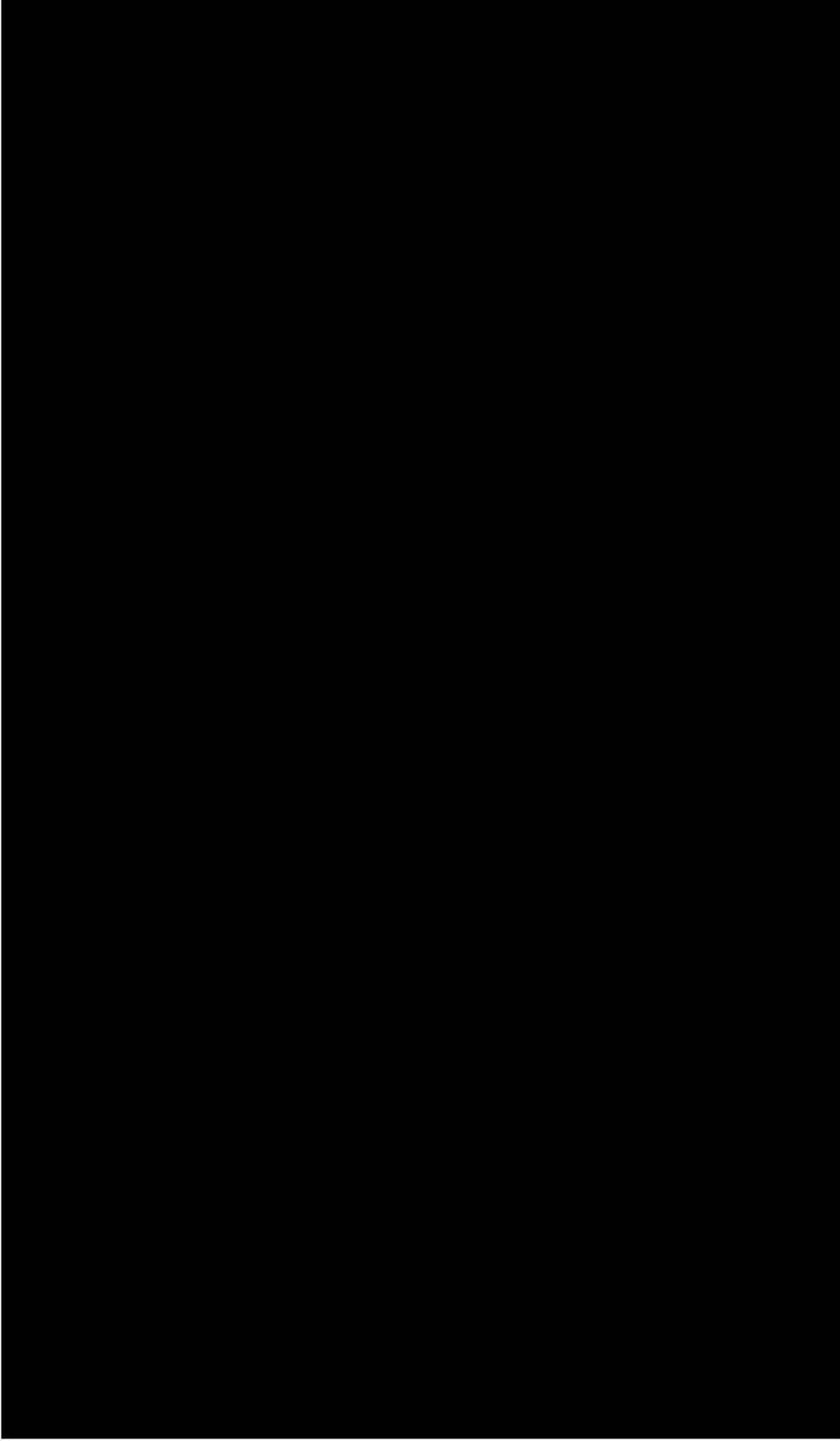


- Thanked sales teams for their commitment to compliance
  - Timely completion of CIA training
  - Professionalism in appropriate and lawful promotion
- Reinforced the importance of compliance
  - Knowledge, awareness, and application of compliance training and product information is Purdue's – and the rep's! – best defense
  - Staying focused on approved messages and materials
- Key reminders
  - Administrative tasks impact compliance
  - Adverse Events, Product Complaints, Reports of Concern, and Abuse & Diversion Detection reporting (Dilaudid, too)
  - Study compliance scenarios
  - Institutional policies for home office review
  - Changes to expense attribution policies

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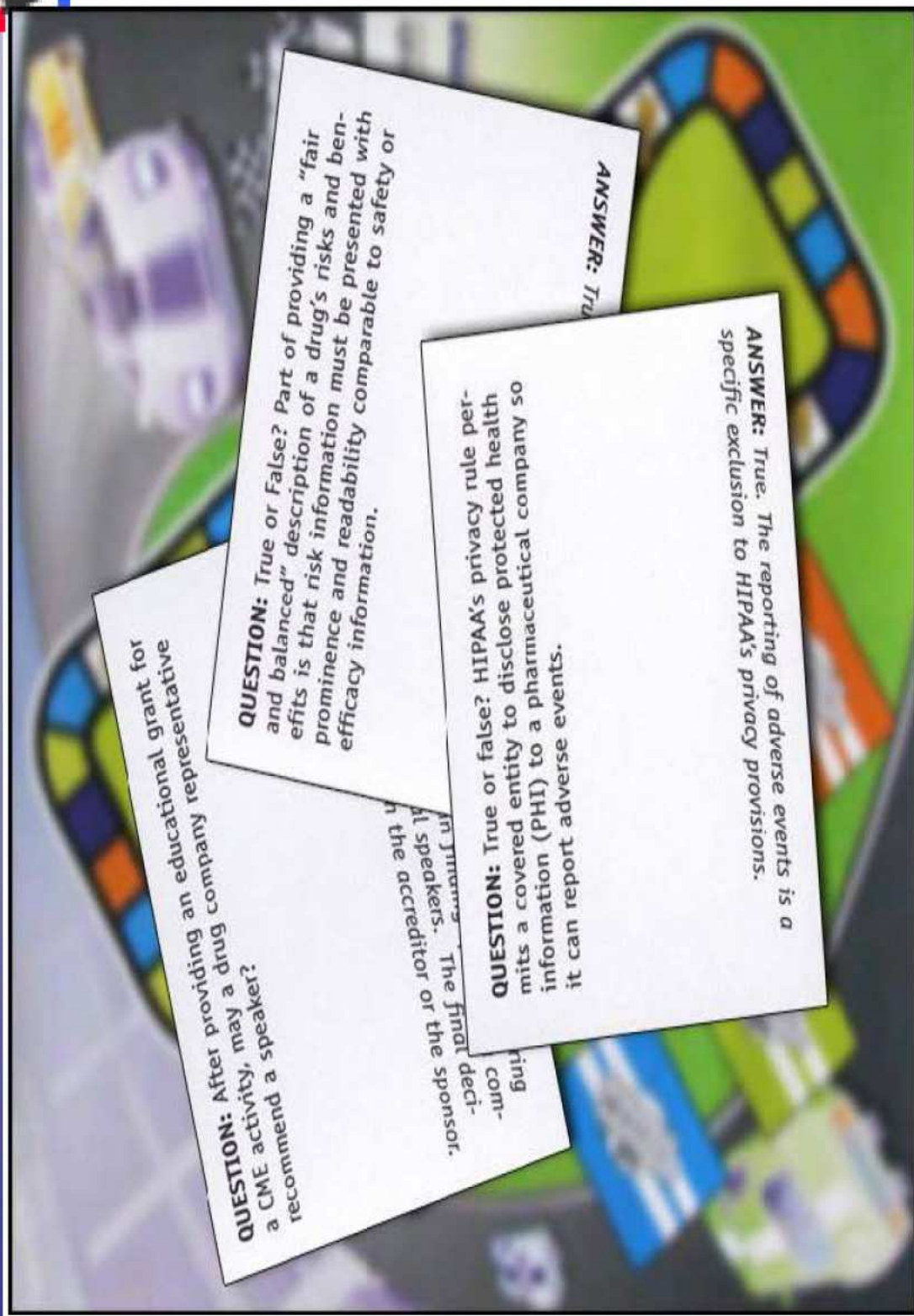
# Compliance Speedway Game

*The Competition was Fierce, as Districts Faced Off!*



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# From 'Compliance Speedway'



**QUESTION:** After providing an educational grant for a CME activity, may a drug company representative recommend a speaker?

**QUESTION:** True or False? Part of providing a "fair and balanced" description of a drug's risks and benefits is that risk information must be presented with prominence and readability comparable to safety or efficacy information.

**QUESTION:** True or false? HIPAA's privacy rule permits a covered entity to disclose protected health information (PHI) to a pharmaceutical company so it can report adverse events.

**ANSWER:** True. The reporting of adverse events is a specific exclusion to HIPAA's privacy provisions.

**ANSWER:** True



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# 2008 Workplan Under Development

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# 2008 Workplan Under Development



- Compliance with CIA



# 2008 Workplan Under Development



- Compliance beyond the CIA is Equally Important:
  - Addressing Risks through Compliance Committees / Compliance Council
    - Sales - Monitoring of field sales call notes, expenses
    - R&D - Focusing on patient/subject safety, CRO involvement in trials, reporting of clinical trial results
    - Quality & Manufacturing – GMP, GLP
  - Auditing and monitoring
    - Based on detected weaknesses
    - Based on evaluation of compliance risk areas
  - Development of new, creative, and engaging compliance training
  - Compliance with federal, state and institutional requirements
  - Development of new Compliance Scorecard – inputs and scoring

# 2008 Workplan Under Development

- Sales District meetings and Representative ride-alongs
- Visibility at each Purdue site
- Weekly Grant Review Committee meetings
- Compliance Investigations
- Sales and Marketing compliance workshops; 25+ Sales Representative training programs
- Monthly meetings with CSA Compliance, EHS, Quality, etc.
- Monitoring of compliance enforcement trends, CIAs
- Communications with Employees
- Employee opinion survey, conflict of interest survey
- Industry compliance leadership roles